



JOSEPH R. BIDEN, III  
ATTORNEY GENERAL

DEPARTMENT OF JUSTICE  
820 NORTH FRENCH STREET  
WILMINGTON, DELAWARE 19801

CONTACT JASON MILLER  
PUBLIC INFORMATION OFFICER  
PHONE (302) 577-8949  
CELL (302) 893-8939  
Jason.Miller@state.de.us

**Media Release**  
October 7, 2008

**Department of Justice announces record settlement with Eli Lilly in drug marketing case**

**Wilmington, DE** – The Delaware Department of Justice announced today that Delaware has reached a record \$62 million dollar settlement with Eli Lilly and Company arising from alleged improper marketing of the antipsychotic drug Zyprexa. The agreement, reached with 32 states and the District of Columbia, is the largest ever multi-state consumer protection pharmaceutical settlement.

“Today’s agreement protects Delaware’s consumers by ensuring that they benefit from full disclosure when making pharmaceutical drug treatment decisions,” stated Fraud and Consumer Protection Division Director Timothy Mullaney.

Delaware and the participating states allege that Eli Lilly engaged in unfair and deceptive practices when it marketed Zyprexa for off-label uses and for failing to adequately disclose its potential side effects to health care providers. In addition to its payments to the states, Eli Lilly will change how it markets Zyprexa and cease promoting its “off-label” uses, which are not approved by the U.S. Food and Drug Administration (FDA). The Delaware Consumer Protection Fund will receive \$966,000.

Zyprexa, the brand name for the prescription drug olanzapine, was first marketed in 1996 for use in adults with schizophrenia. Since then the FDA has also approved its use for the treatment of bipolar disorder. Zyprexa belongs to a class of drugs, traditionally used to treat schizophrenia, that were thought to be less likely to produce symptoms such as those seen in Parkinson’s disease and in motion disorders. While they may reduce the risk of these symptoms, these drugs also produce dangerous side effects, including weight gain, hyperglycemia, diabetes, cardiovascular complications, and an increased risk of mortality in elderly patients with dementia. Zyprexa has been associated with a high risk of weight gain, hyperglycemia, and diabetes.

In 2001, Eli Lilly began to aggressively market Zyprexa for a number of off-label uses, including for children, elderly patients suffering from dementia, and the treatment of symptoms rather than diagnosed conditions. While physicians may prescribe drugs for off-label uses, pharmaceutical manufacturers are prohibited by law from marketing their products for off-label uses.

Under today's agreement, for six years beyond the patent term for Zyprexa Eli Lilly will, among other things:

- Only provide product samples of Zyprexa to a health care provider whose clinical practice is consistent with its current labeling
- Not promote Zyprexa for selected symptoms of the FDA-approved diagnoses unless disclosures are made regarding the approved diagnoses
- Not use in a promotional manner article reprints containing more than an incidental reference to off-label information regarding Zyprexa
- Require its medical staff, rather than its marketing staff, to be responsible for developing and approving the medical content for all medical letters and medical references regarding Zyprexa
- Contractually require continuing medical education providers to disclose Eli Lilly's financial support of their programs and any financial relationship with faculty and speakers
- Provide each Attorney General participating in today's agreement with a list of health care provider promotional speakers and consultants who Eli Lilly paid more than \$100 for promotional speaking and/or consulting

# # #